



BILLING CODE 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2016-0500; FRL-9964-21]**

### **Potassium Salts of Naphthalenesulfonic Acids Formaldehyde Condensates; Exemption from the Requirement of a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of naphthalenesulfonic acids formaldehyde condensates, potassium salts (CAS Reg. No. 67828-14-2) when used as an inert ingredient (surfactant and related adjuvant of surfactants) applied to growing crops and raw agricultural commodities after harvest by amending an existing exemption for similar substances. Monsanto Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting this amendment. This regulation eliminates the need to establish a maximum permissible level for residues of naphthalenesulfonic acids formaldehyde condensates, potassium salts, when used consistent with the terms.

**DATES:** This regulation is effective *[insert date of publication in the Federal Register]*.

Objections and requests for hearings must be received on or before *[insert date 60 days after date of publication in the Federal Register]*, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2016-0500, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDfRNotices@epa.gov](mailto:RDfRNotices@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).

- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2016-0500 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2016-0500, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Petition for Exemption**

In the **Federal Register** of October 18, 2016 (81 FR 71668) (FRL-9952-19), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10965) by Monsanto Company, 1300 I (Eye) Street, NW, Washington, D.C. 20005. The petition requested that the existing exemption for residues of mono-, di-, and trimethylnaphthalenesulfonic acids and naphthalenesulfonic acids formaldehyde condensates, ammonium and sodium salts (CAS Reg. Nos. 9008-63-3, 9069-80-1, 9084-06-4, 36290-04-7, 91078-68-1, 141959-43-5, 68425-94-5) in 40 CFR 180.910 be amended to also exempt residues of the potassium salts (CAS Reg. No. 67828-14-2) when used as an inert ingredient (i.e., as a surfactant or related adjuvant of surfactants) in pesticide formulations applied to growing crops or raw agricultural commodities after harvest. That document referenced a summary of the petition prepared by Monsanto Company, the petitioner, which is available in the docket, <http://www.regulations.gov>. One comment was received on the notice of filing. EPA's response to that comment is discussed in Unit V.C.

## **III. Inert Ingredient Definition**

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons;

surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

#### **IV. Aggregate Risk Assessment and Determination of Safety**

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as

a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for naphthalenesulfonic acids formaldehyde condensate potassium salt including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with naphthalenesulfonic acids formaldehyde condensate potassium salt follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

In the **Federal Register** of October 7, 2009 (74 FR 51470) (FRL-8439-1), EPA established an exemption from the requirement of a tolerance for the sodium and ammonium salts of naphthalenesulfonate formaldehyde condensates (SANFC). In the preamble to that rule, EPA concluded that there were no adverse effects observed in the available database.

Naphthalenesulfonic acids formaldehyde condensate potassium salt differs from sodium and ammonium salts of naphthalenesulfonate formaldehyde condensates, only in the counterion (i.e., potassium versus sodium and ammonium) and would all share the same toxicity profile.

Specific information on the studies received and the nature of the adverse effects caused by naphthalenesulfonic acids formaldehyde condensate potassium salt as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in the **Federal Register** of October 7, 2009 (74 FR 51470) (FRL-8439-1).

*B. Toxicological Points of Departure/Levels of Concern*

Based on the low potential hazard and the lack of a hazard endpoint for these compounds, EPA determined that a quantitative risk assessment is not appropriate.

*C. Aggregate Exposures*

In examining aggregate exposure, section 408 of FFDCa directs EPA to consider available information concerning exposures from the pesticide residue in food and all other nonoccupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

No hazard was identified for the acute and chronic dietary assessment (food and drinking water), or for the short term, intermediate-term, and long-term residential assessments, and therefore, no quantitative aggregate exposure assessments were performed. The Agency qualitatively assessed exposure as follows. When used in pesticide formulations applied to growing crops and raw agricultural commodities after harvest, there may be exposure from residues in or on food and from residues ending up in drinking water from use on growing crops. The SANFC inerts are used as dispersants, defoamers and emulsifiers in pesticide formulations. These surfactants have a wide range of industrial uses as well as serving as emulsifiers in personal care products and in food contact packaging; therefore, EPA concludes that exposure from these sources is also likely.

*D. Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found naphthalenesulfonic acids formaldehyde condensate potassium salt to share a common mechanism of toxicity with any other substances, and naphthalenesulfonic acids formaldehyde condensate potassium salt does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that naphthalenesulfonic acids formaldehyde condensate potassium salt does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

*E. Determination of Safety*

Based on all available information, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to residues of the potassium salt of naphthalenesulfonic acids formaldehyde condensates, when used as inert ingredients in pesticide formulations applied to growing crops and raw agricultural commodities after harvest.

**V. Other Considerations**

*A. Analytical Enforcement Methodology*



An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

#### *B. Response to Comments*

One comment was received for a notice of filing offering suggestions on how to move away from using synthetic chemicals as pesticides. This comment is not specifically directed at today's tolerance exemption action nor does it include any information for the Agency to consider in making its safety determination for this exemption.

### **VI. Conclusions**

Therefore, the existing exemption from the requirement of a tolerance in 40 CFR 180.910 for residues of mono-, di-, and trimethylnaphthalenesulfonic acids and naphthalenesulfonic acids formaldehyde condensates, ammonium and sodium salts is amended to include potassium salts (specifically, naphthalenesulfonic acids formaldehyde condensate potassium salt (CAS Reg. No. 67828-14-2)) when used as an inert ingredient (surfactant and related adjuvant of surfactant) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest.

### **VII. Statutory and Executive Order Reviews**

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045,

entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

#### **VIII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 18, 2017.

Donna S. Davis,  
*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In §180.910, revise the existing entry for “Mono-, di-, and trimethylnaphthalenesulfonic acids and naphthalenesulfonic acids formaldehyde condensates, ammonium and sodium salts (CAS Reg. Nos. 9008-63-3, 9069-80-1, 9084-06-4, 36290-04-7, 91078-68-1, 141959-43-5, 68425-94-5)” to read as follows:

**§ 180.910 Inert ingredients used pre- and post-harvest; exemption from the requirement of a tolerance.**

\* \* \* \* \*

Inert ingredients	Limits	Uses
* * *	* * *	*
Mono-, di-, and trimethylnaphthalenesulfonic acids and naphthalenesulfonic acids formaldehyde condensates, ammonium, sodium and potassium salts (CAS Reg. Nos. 9008-63-3, 9069-80-1, 9084-06-4, 36290-04-7, 91078-68-1, 141959-43-5, 68425-94-5, 67828-14-2)		Surfactants, related adjuvants of surfactants
* * *	* * *	*